

## REMARKS

Claim 51 has been amended to specify that the therapeutic composition is to be administered to a cancer patient. Support is found in the claim itself, in its recitation of a cancerous condition. None of the amendments made herein constitute the addition of new matter.

### The Objection to the Specification

The Examiner has objected to the title of the application, alleging that it is not description of the invention as claimed.

In the interest of advancing prosecution and without acquiescing to the rejection, Applicants have amended the title as suggested by the Examiner.

### The Rejections under 35 U.S.C. 112, first paragraph

Claims 51-58 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly not enabling for prophylaxis (i.e., prevention) of a cancer condition. Applicants respectfully traverse this rejection.

The Patent Office has conceded that the Specification enables treatment of a cancerous condition.

In the interest of advancing prosecution and without acquiescing to the rejection, Applicants have amended claim 51 to delete recitation of prophylaxis and to specify that the composition is administered to a cancer patient.

In view of the foregoing, Applicants respectfully state that the claims should be deemed to meet the requirements of Section 112, and this rejection should be withdrawn.

### The Rejections under 35 U.S.C. 102

Claims 51-55 have been rejected under 35 U.S.C. 102(b), as allegedly anticipated by Sartori (2000). Applicants respectfully traverse this rejection.

The Patent Office has characterized Sartori as teaching a clinical trial in which 200 breast or colon cancer patients were pretreated with omeprazole daily for seven days before chemotherapy was started. Chemotherapy consisted of cyclophosphamide, methotrexate and fluorouracil for breast cancer patients and of fluorouracil for the colon cancer (i.e., adenocarcinoma) patients. The Patent Office has also stated that the statement of the intended use does not limit the present claimed invention.

The Examiner appears to have interpreted the wording 'a method for treatment...of a cancerous condition...' as meaning 'a method suitable for treatment...of a cancerous condition...', and thus believes that the nature of the condition treated is non-limiting. Applicants respectfully note that it is intended that the present claims are limited by recitation of the use of proton pump inhibitors to treat a cancerous condition, since it is this particular use which is novel over the prior art. As noted by the Examiner, Sartori discloses the use of proton pump inhibitors to reduce the frequency of injury to the gastrointestinal tract caused by chemotherapy. The Sartori study merely evaluated the occurrence of chemotherapy-induced ulcers, heartburn or pain in patients receiving proton pump inhibitors compared to those receiving a placebo. The paper does not disclose or suggest that the proton pump inhibitors have an effect on the cancer itself, as has surprisingly been found by the present inventors.

However, in order to clarify the limitation of method claim 51 to treatment of a cancerous condition, claim 51 has been amended to recite 'a method of treatment of a cancerous condition...comprising the step of oral administration of a therapeutic composition comprising a proton pump inhibitor to a cancer patient in need thereof'.

In view of the foregoing, Applicants respectfully maintain that the present invention is novel over the prior art and that the rejection should be withdrawn.

#### The Rejections under 35 U.S.C. 103

Claims 56-58 have been rejected under 35 U.S.C. 103, as allegedly obvious over by Sartori (2000) as applied to claims 51-55 above and Phillips (US 2003/0191159; US 6,699,885). Applicants respectfully traverse this rejection.

These claims relate to the co-administration of an antacid such as calcium carbonate along with the proton pump inhibitor. The Phillips patent concerns methods comprising administering a proton pump inhibitor in combination with a buffering agent such as calcium carbonate, with the aim of treating an acid-related disorder (i.e., a acid-related stomach disorder) or improving absorption of the proton pump inhibitor. Neither Sartori nor Phillips discloses or suggests that proton pump inhibitors, either alone or in combination with other compounds, would be useful to treat cancerous conditions. Furthermore, the skilled person would not be motivated to combine the teachings of the two cited documents which are from different technical fields, Sartori relating to the prevention of chemotherapy-side effects, while Phillips relates to the treatment of acid-related disorders such as ulcers and reflux, not related to chemotherapy side effects. However, even if the skilled person were to combine these documents, they would not arrive at a method of treating cancer comprising administering proton pump inhibitors, because neither document suggests that proton pump inhibitors themselves are effective against cancers, as has been found by the present inventors. Claim 51, and all claims dependent thereon, are therefore non-obvious in view of the prior art. The same argument applies in response to the Examiner's objection that claims 56 to 58 are obvious in view of the combination of commercially available proton pump inhibitors (e.g., omeprazole) and antacids (e.g., TUMS), which again are known in combination for the treatment of such problems as acid indigestion, but not cancer.

In view of the foregoing, Applicants respectfully submit that the present invention as claimed is not *prima facie* obvious over the cited art, and thus, the rejection must be withdrawn.

### Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

It is believed that the present amendment does not require the payment of any fees pursuant to 37 C.F.R. 1.16-1.17. If this is incorrect, however, please charge any fees due under the foregoing Rules to Deposit Account No. 07-1969 and grant any extension of time, if needed.

Respectfully submitted,

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